IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

MYLAN PHARMACEUTICALS INC., MYLAN SPECIALTY L.P., and MYLAN INC., *Plaintiffs*, v. SANOFI-AVENTIS U.S. LLC, SANOFI S.A., AVENTIS PHARMA S.A., and SANOFI-AVENTIS PUERTO RICO INC. *Defendants*.	No. 2:23-cv-00836-MRH

MEMORANDUM IN SUPPORT OF
DEFENDANTS' MOTION TO DISMISS PLAINTIFFS' COMPLAINT

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INTRODUCTION

Mylan's complaint is a mishmash of unsupported theories and antitrust buzz words that fail to state a claim as a matter of law. Plaintiffs (collectively, "Mylan") allege that Sanofi-Aventis U.S. LLC and three of its corporate affiliates (collectively, "Sanofi") monopolized the market for "injectable insulin glargine" to protect their sales of Lantus® and Toujeo® and exclude Mylan's competing product, Semglee. One of Mylan's two primary theories—that Sanofi used "bundled" discounts to tie Lantus and Toujeo and exclude Semglee from the market—fails for at least four reasons. *First*, it fails as a matter of law because the complaint never alleges (as it must) that Sanofi bundled products across two different product markets. *Second*, Mylan tries to supplement its bundling theory with a conclusory allegation of an express exclusive dealing agreement, and a few nonsensical allegations of a "coercive product hop," all of which fail to plausibly support (let alone state) a claim. *Third*, Mylan fails to plead the required element of substantial foreclosure of the market. *Fourth*, Mylan fails to plausibly allege market power in a relevant market, which requires dismissal of the bundling theory and the entire monopolization claim.

Mylan's other theory is that Sanofi caused the Food and Drug Administration (FDA) to delay approval of Semglee by improperly listing patents in the agency's "Orange Book" and then asserting those patents in sham litigation against Mylan in order to trigger a statutory 30-month stay of FDA approval of Semglee. This theory has three foundational flaws. *First*, a claim concerning the 2013 patent listings and 2017 patent litigation is time-barred. *Second*, Mylan fails to plausibly allege that *Sanofi* caused FDA to delay Semglee's approval. Instead, Mylan's allegations, along with FDA's public records (of which the Court can take judicial notice), demonstrate that Mylan's *own* business decisions and failures—not the patent litigation—delayed FDA approval of Semglee. *Third*, independently, the sham litigation theory fails because Mylan does not plausibly allege that Sanofi's patent litigation was objectively baseless.

For all of these reasons, Mylan's claim under section 2 of the Sherman Act, along with its follow-on claims under federal and state law, must be dismissed for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6). And even if Mylan had stated a claim against the hypothetical "Sanofi"—which the complaint defines as an amalgamation of the four defendants—the complaint fails to state a claim against each individually, because it does not attempt to plead that each defendant took actions giving rise to a claim for relief.

In addition, the complaint must be dismissed as to Sanofi S.A. for lack of personal jurisdiction under Federal Rule of Civil Procedure 12(b)(2). To carry its burden to establish personal jurisdiction, Mylan must allege that each defendant had requisite minimum contacts with the United States. But, other than to allege it is headquartered in France, the complaint lacks even a single allegation about the activities of Sanofi S.A., instead lumping the defendants together as "Sanofi," without even attempting to differentiate between them, or to allege (as Mylan must) that Sanofi S.A. took affirmative and specific steps to effectuate the alleged "scheme." This is facially deficient as a matter of law, and the complaint must be dismissed as to Sanofi S.A. for this reason as well.

LEGAL STANDARD

"To survive a motion to dismiss, a complaint must contain sufficient factual matter … to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). This requires factual allegations establishing all elements of a cause of action. *See Santiago v. Warminster Twp.*, 629 F.3d 121, 130 (3d Cir. 2010). "Threadbare recitals" of the elements, "conclusory statements" of fact, and mere "legal conclusions" "do not suffice" and are not accepted as true. *Iqbal*, 556 U.S. at 678. The allegations must "raise a right to relief above the speculative level," meaning that they must render the claim not merely "conceivable," but "plausible." *Twombly*, 550 U.S. at 555, 570.

ARGUMENT

I. MYLAN FAILS TO STATE A MONOPOLIZATION CLAIM UNDER THE SHERMAN ACT

Mylan's lead claim attempts—but fails miserably—to allege monopolization under section 2 of the Sherman Act. Compl. ¶ 234. To state a monopolization claim, a plaintiff must plausibly allege that the defendant possessed "monopoly power" in a relevant market and engaged in anticompetitive conduct. *Pac. Bell Tel. Co. v. linkLine Commc'ns, Inc.*, 555 U.S. 438, 447-48 (2009); *see Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 402-03 (3d Cir. 2016) (discussing the element of "anticompetitive conduct"). A plaintiff must also allege "antitrust injury," which means injury to competition. *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977). And a plaintiff must plead causation—a "causal connection between the purportedly unlawful conduct and the injury." *City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256, 265 (3d Cir. 1998). Mylan's section 2 claim must be dismissed in its entirety because each of its theories, considered separately or together, fails one or more of these required elements.

A. Mylan's Bundled-Discount Theory Fails To Allege Exclusionary Conduct Or Substantial Foreclosure Of A Market

Mylan's primary theory is that Sanofi excluded Semglee from the market by conditioning discounts for Lantus and Toujeo on "the inclusion of both" drugs on pharmaceutical formularies maintained by Pharmacy Benefit Managers (PBMs). Compl. ¶ 219; *see id.* ¶ 201 (heading L). According to Mylan, Sanofi used "bundling and conditional rebates" to coerce PBMs to purchase both Lantus and Toujeo, and not to purchase Semglee. *Id.* ¶ 208. Mylan invokes a litany of ominous terms to describe this theory: a "coercive market switch," a "coercive product hop," "bundling," "pairing," and "tying." *Id.* ¶¶ 3, 8, 13, 206, 208, 223. Shorn of empty labels, however, Mylan's theory boils down to allegations of exclusive dealing based on "bundled rebates." *LePage's Inc. v. 3M*, 324 F.3d 141, 154 (3d Cir. 2003) (en banc); *see also Cascade Health Sols. v.*

PeaceHealth, 515 F.3d 883, 894 (9th Cir. 2008) (analyzing "when bundled discounting can amount to anticompetitive conduct").

An exclusive dealing claim requires allegations of (1) some form of exclusive dealing arrangement, and (2) "substantial foreclosure" of the market, meaning the defendant entered into exclusive dealing arrangements with such a high proportion of buyers that it "severely restrict[ed] the market's ambit." *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 270-71 (3d Cir. 2012). Mylan comes nowhere close to plausibly alleging either element.

1. *The complaint fails to allege exclusionary conduct required for a bundling claim.*

"A bundled discount occurs when a firm sells a bundle of goods or services for a lower price than the seller charges for the goods or services purchased individually." *Cascade Health*, 515 F.3d at 894. "Bundled discounts generally benefit buyers because the discounts allow the buyer to get more for less." *Id.* at 895. In narrow circumstances, "bundled rebates and discounts" can "operate as exclusive dealing arrangements," *ZF Meritor*, 696 F.3d at 282, but this is "limited to cases in which a *single-product producer* is excluded through a bundled rebate program offered by a producer of multiple products, which conditions the rebates on purchases across *multiple different product lines*," *id.* at 274 n.11 (emphasis added); *see Eisai*, 821 F.3d at 405 (affirming this holding of *ZF Meritor*).

Bundling claims derive from "unlawful tying," which "cannot exist unless two separate product markets have been linked." *ZF Meritor*, 696 F.3d at 274 n.11 (quoting *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 21 (1984)); *LePage's*, 324 F.3d at 155 (noting that bundling claims "are best compared with tying"). And competitive concerns about bundling arise only when the defendant's competitor "does not manufacture an equally diverse group of products and … therefore cannot make a comparable offer" for bundled discounts. *LePage's*, 324 F.3d at 155; *see*

Cascade Health, 515 F.3d at 897 ("[A] bundled discounter can exclude rivals who do not sell as great a number of product lines without pricing its products below its cost to produce them.").

Crucially, a different legal test for anticompetitive conduct—the "price-cost test" used for predatory pricing claims—applies when a plaintiff alleges discounts in a *single* product market. *ZF Meritor*, 696 F.3d at 274 n.11 ("Accordingly, we join our sister circuits in holding that the price-cost test applies to market-share or volume rebates offered by suppliers within a single-product market."). The price-cost test requires allegations that the defendant priced its goods below cost and had "a dangerous probability … of recouping its investment in below-cost prices" after its rival exited the market. *Id.* at 272.

a. ***Mylan fails to allege bundling across two separate product markets.*** Here, Mylan's complaint boils down to a theory of single-product rebates, which fails as a matter of law. Rather than alleging bundling of products in "separate product markets," *id.* at 274 n.11, the complaint takes great pains to allege that Lantus and Toujeo are the *same product* competing to fill the *same consumer demand*. Toujeo is, allegedly, "therapeutically indistinguishable" from Lantus, with "no unique therapeutic value." Compl. ¶¶ 3, 8, 22, 197, 202; *see also id.* ¶ 14 (no "patient benefit or medical necessity"). Customers allegedly are unwilling to pay more for Toujeo than Lantus because there is little additional benefit. *Id.* ¶¶ 12, 201. FDA itself allegedly found little difference between the drugs. *Id.* ¶ 196. And, according to Mylan, Sanofi believes that Toujeo and Lantus compete to fulfill the same demand and sought to "convert" Lantus users to Toujeo. *Id.* ¶¶ 12-14, 199-200.

Thus, in Mylan's own view of the world, Semglee competes directly with *both* Lantus and Toujeo, all in a single product market. According to Mylan, Lantus and Toujeo are perfect substitutes, and Semglee is biosimilar to (and since July 2021, interchangeable with) Lantus. *Id.*

¶¶ 15, 123, 138. Even the complaint's proposed market definition, "injectable insulin glargine," lumps all three products together by explicitly including "Lantus and Toujeo and their 'generic' or biosimilar equivalents." *Id.* ¶¶ 212, 215. Thus, the assertion that "Mylan did not, and does not, offer a competing product to Toujeo" (*id.* ¶ 210) is irreconcilable with Mylan's own description of the drugs and its alleged market definition, and cannot be credited. *See Dorley v. S. Fayette Twp. Sch. Dist.*, 129 F. Supp. 3d 220, 236 (W.D. Pa. 2015) ("[L]egal conclusions, or conclusory facts, may not contradict the detailed factual allegations of the Complaint."); *see also Bocker v. Hartzell Engine Techs., LLC*, 2023 WL 415792, at *4 & n.11 (D. Del. Jan. 26, 2023) ("Where a plaintiff's own pleading is internally inconsistent and contradictory, the court is not obligated to reconcile or accept such contradictory allegations.").

Because Semglee competes directly with both Lantus and Toujeo, Mylan *can* make a "comparable offer" for a discount without involving a second product market, unlike the plaintiff in *LePage's*, 324 F.3d at 155. There, LePage's could not compete with 3M's aggregate discount on tape and health care products because LePage's made only tape. *Id.* at 144-45. Here, Mylan can compete with Sanofi's aggregate discount on Lantus and Toujeo because Mylan's Semglee competes with both. If Sanofi offers an aggregate discount on 100 units of Lantus and 100 units Toujeo, Mylan can match the deal by offering the same discount on 200 units of Semglee. Thus, Mylan's allegation that "[i]t was economically impossible" for it to "cover this difference in a vacuum" (Compl. ¶ 17) is implausible, and fails the "common sense" test under *Iqbal*, 556 U.S. at 679.

Accordingly, Mylan's bundling claim fails as a matter of law because Mylan fails to allege bundling of products in "separate product markets." *ZF Meritor*, 696 F.3d at 274 n.11. Moreover, Mylan's failure to plead separate product markets means the price-cost test applies, *ZF Meritor*,

696 F.3d at 274 n.11, and Mylan does not even attempt to allege that Sanofi priced Lantus and Toujeo below cost. Quite the contrary, Mylan alleges that "Sanofi sold Lantus and Toujeo at prices well in excess of marginal costs," *see* Compl. ¶ 216.

Separately, Mylan alleges that Sanofi bundled rebates in contracts with State entities, such as Medicaid programs. *See* Compl. ¶¶ 15, 200, 226. That subset of Mylan's claims is barred by the *Noerr-Pennington* doctrine, under which a plaintiff cannot complain about "restraint[s] upon trade or monopolization" that are "the result of governmental action." *E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 136 (1961); *see Asphalt Paving Sys., Inc.*, *v. Asphalt Maint. Sols., LLC*, 2013 WL 1292200, at *4-7 (E.D. Pa. Mar. 28, 2013). Because Medicaid formularies are an outcome of governmental processes, *Noerr-Pennington* bars Mylan's claims based on discounts or rebates paid to those agencies. *See, e.g.*, *In re EpiPen Mktg., Sales Practices & Antitrust Litig.*, 336 F. Supp. 3d 1256, 1290-91 (D. Kan. 2018).

b. ***Mylan is not a single-product competitor.*** Mylan's bundling theory fails for the independent reason that it cannot plausibly allege it is a "single-product" competitor. *ZF Meritor*, 696 F.3d at 274 n.11. Because Mylan manufactures products other than Semglee, it can bundle Semglee discounts with discounts on those products to make a comparable offer to the discounts Sanofi offers for Lantus and Toujeo. *See Pfizer Inc. v. Johnson & Johnson*, 333 F. Supp. 3d 494, 503-04 (E.D. Pa. 2018) ("Pfizer, of course, is not a single-product producer. … J & J's multi-product bundles, on their own, therefore do not present antitrust concern."). While Mylan alleges it is a "single-product competitor," Compl. ¶ 13, this allegation fails to meet Rule 11 and need not be credited. For example, the complaint incorporates a Mylan press release explaining that Mylan manufactures "more than 1,100 generic pharmaceuticals and several brand medications." *See id.* ¶ 124 n.24. Further, FDA's Orange Book—a judicially noticeable public record (*see infra* p. 19)—

reveals that the Mylan plaintiffs had more than 300 drug products approved for sale in the United States in 2020, including at least 25 branded drugs.[1] This includes Mylan's popular "EpiPen" injector. *See In re EpiPen Mktg., Sales Practices & Antitrust Litig.*, 44 F.4th 959 (10th Cir. 2022).

Mylan's dozens of product lines are obviously as diverse (if not more so) than Sanofi's two-product Lantus-Toujeo bundle. Thus, if Mylan was for some reason unable to offer a competing discount bundle, it was required (and failed) to allege plausible facts in support of such a conclusion. *Pfizer*, 333 F. Supp. 3d at 504 ("Pfizer has not alleged any facts suggesting that J & J is hindering its ability to compete with J & J's multi-product bundles by offering their own multi-product bundles."); *Shire US, Inc. v. Allergan, Inc.*, 375 F. Supp. 3d 538, 557 (D.N.J. 2019) ("Plaintiff—a large pharmaceutical company—has also not asserted that it did not have other available products that it could offer … as part of a bundled rebate."). Between two multi-product competitors like Sanofi and Mylan, bundled rebates merely represent "vigorous price competition," and do not state an antitrust claim as a matter of law. *EpiPen*, 44 F.4th at 1000.

c. ***Mylan's other exclusionary conduct allegations are wholly conclusory.*** Mylan unsuccessfully attempts to bolster its bundling theory with two other conclusory allegations of exclusionary conduct. *First*, a single sentence in Mylan's complaint alleges that Sanofi "conditioned rebates for Toujeo on PBMs' agreement to *exclude* biosimilar insulin glargine products from formularies." Compl. ¶ 11 (emphasis added). But Mylan never pleads any facts in support of this allegation, such as alleging the existence of a specific exclusivity agreement, the PBM with whom any such agreement existed, when it was adopted, or how long it was in effect.

[1] FDA, *Approved Drug Products With Therapeutic Equivalence Evaluations* ("Orange Book"), Appendix B, at 120-27 (40th ed. 2020), https://wayback.archive-it.org/7993/20201222044046/https:/www.fda.gov/media/71474/download (**Exhibit A**) (highlighting in yellow the Mylan plaintiffs and in pink the branded drugs).

Furthermore, Mylan's repeated allegation that Sanofi conditioned its rebates on *inclusion* of Lantus and Toujeo on formularies does not save this solitary *exclusion* allegation, because Mylan never alleges that including Lantus and Toujeo on formularies meant excluding other products. *See, e.g.*, *id.* ¶ 219 ("conditioning rebates for either product on the inclusion of both on formularies"); *accord id.* ¶¶ 3, 10, 11, 17, 203, 204, 247; *see id.* ¶ 201 (heading L) ("Sanofi Conditioned Rebates for Lantus on the Inclusion of Toujeo").

Second, Mylan gets nowhere by sprinkling conclusory allegations of a "coercive product hop." Compl. ¶¶ 8, 223, 236, 252. The complaint does not try to allege a viable product-hopping claim, which would require (at minimum) an allegation that Sanofi "withdrew" Lantus "from the market," resulting in a "hard switch" to Toujeo. *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 648, 655 (2d Cir. 2015); *see also Mylan Pharms. Inc. v. Warner Chilcott Pub. Ltd. Co.*, 838 F.3d 421, 429 (3d Cir. 2016) ("*Doryx*") (rejecting product-hopping claim, even where Mylan alleged that defendant "pulled older versions [of the drug] from the market"); *In re Asacol Antitrust Litig.*, 233 F. Supp. 3d 247, 269 (D. Mass. 2017) (collecting cases, and dismissing product-hopping claim because defendant "maintained both products on the market"). Here, the complaint alleges the opposite of a product hop: Sanofi allegedly used bundling to ensure Lantus *remained available*. *See* Compl. ¶ 3 ("the tying of rebates began to work in reverse, with Toujeo protecting Lantus"). Indeed, not only does Lantus remain on the market, but the complaint alleges that it was still far outselling Toujeo in 2020. Compl. ¶ 18.

2. *The complaint fails to plausibly allege market foreclosure.*

Mylan's bundling theory also must be dismissed for failing to plausibly allege "substantial foreclosure" of the market. *ZF Meritor*, 696 F.3d at 271. "To demonstrate substantial foreclosure, a plaintiff 'must both define the relevant market and prove the degree of foreclosure.'" *Eisai*, 821 F.3d at 403. The challenged practice must "bar a substantial number of rivals or severely restrict

the market's ambit." *Id.* Here, the complaint not only fails to plausibly allege a relevant market, as discussed below (p. 11), but it fails to allege any degree of foreclosure. For example, the complaint fails to allege basic facts about the market that would permit a plausible inference of market foreclosure, such as how many PBMs exist, whether there are other buyers besides PBMs, whether Sanofi entered into agreements with a large proportion of buyers, how many rivals exist, and whether Sanofi's alleged bundled discounts excluded a substantial portion of the market from those rivals.

Worse still, the complaint admits the presence of other market rivals that have *not* been foreclosed. Eli Lilly introduced a competing insulin glargine, Basaglar, in 2016. Compl. ¶¶ 194, 214. Novo Nordisk has long sold a basal insulin, Levemir. *Id.* ¶ 194. Despite knowing this, Mylan fails to allege whether and to what extent Sanofi's conduct affected *the market*, including other rivals. *Cf.* Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application*, ¶ 749d (4th ed. 2022) ("[W]e would not extend the [bundled-discount] doctrine to any situation in which there was at least one competing firm able to match the defendant's discount across all product lines."). The complaint similarly fails to allege whether Sanofi's conduct "restrict[ed] the market's ambit," that is, whether any buyers were "reasonably available" to competitors. *Eisai*, 821 F.3d at 403. By contrast, in *ZF Meritor*, the defendant entered into agreements with "every direct purchaser in the market." 696 F.3d at 287; *see also United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 196 (3d Cir. 2005) (defendant's "grip on its 23 authorized dealers effectively choked off the market"); *LePage's*, 324 F.3d at 160 (defendant cut off "key retail pipelines").

At bottom, the complaint fails to allege market foreclosure, and for this independent reason the bundling theory and any other exclusive dealing theory must be dismissed.

B. Mylan Fails To Plausibly Define A Relevant Market Or Allege Market Power

Mylan's entire monopolization claim must also be dismissed because the complaint fails to define a relevant market and fails to plausibly allege market power.

1. *The complaint ignores substitute products and therefore fails to define a relevant market.*

Mylan must define the relevant market for two independent reasons. First, claims of monopolization or attempted monopolization require, respectively, proof of market power or a dangerous probability of achieving market power. *Doryx*, 838 F.3d at 433. Direct evidence of market power is "rarely available." *Id.* at 434. More commonly, a plaintiff must rely on "indirect evidence," by showing that the defendant possesses a large share of the relevant market and that there are barriers to entry. *Id.* at 435. This method obviously "requires a definition of the relevant market." *Id.* Mylan contends it need not define the relevant market because it has direct evidence, Compl. ¶¶ 219-20, but its allegations are wholly conclusory, as explained below. And in any event, the complaint must certainly plead a relevant market to show *attempted* monopolization, because "direct measures of market power can, of course, detect only present power," whereas an attempted monopolist seeks to obtain power "that does not yet exist." Areeda & Hovenkamp ¶ 531d.

Second, and independently, the complaint must define the relevant market because, as explained above, Sanofi's alleged exclusive-dealing conduct is only anticompetitive if it resulted in substantial foreclosure of the market, which naturally requires defining the relevant market. *Eisai*, 821 F.3d at 403. Mylan thus cannot possibly escape its burden of plausibly alleging a relevant market. Failing that burden, the monopolization claim must be dismissed.

A relevant market must include all products that are reasonably interchangeable for the same use, based on price, use, qualities, and cross-elasticity of demand. *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 437 (3d Cir. 1997). Products are interchangeable when "either

would work effectively," regardless of "some degree of preference for one product over the other." *Doryx*, 838 F.3d at 436 (cleaned up). If a complaint "alleges a proposed relevant market that clearly does not encompass all interchangeable substitute products," the market definition is "legally insufficient" and the complaint may be dismissed. *Queen City Pizza*, 124 F.3d at 436; *see also, e.g.*, *Re-Alco Indus., Inc. v. Nat'l Ctr. for Health Educ., Inc.*, 812 F. Supp. 387, 391-92 (S.D.N.Y. 1993) (requiring a complaint to "allege facts regarding substitute products" and to "distinguish among apparently comparable products" to avoid dismissal); *N. Penn Towns, LP v. Concert Golf Partners, LLC*, 554 F. Supp. 3d 665, 698-99 (E.D. Pa. 2021) (collecting cases failing to allege facts distinguishing products in proposed market from apparently related products).

Mylan alleges that the relevant market is limited to injectable insulin glargine. Compl. ¶ 220. But it acknowledges that there are "other insulin product[s]." *Id.* ¶ 214. Specifically, Mylan alleges that Lantus fits in the category of "basal" or "long-acting" insulins, *id.* ¶ 89, and repeatedly refers to the category of "basal" insulin, *id.* ¶¶ 8, 12, 14, 89, 195, 201, 208. Mylan alleges that Lantus was competing with basal insulins other than glargine. *Id.* ¶ 14 ("convert basal insulin, especially glargine users"). And the figure in paragraph 194 identifies some non-glargine basal insulins, such as Levemir and Tresiba, with which Lantus and Toujeo compete. The "Drug Pricing Report," which the complaint incorporates by reference, states explicitly that Levemir "competes with Sanofi's long-acting insulin product, Lantus."[2] The "Insulin Report Documents," which the complaint also incorporates by reference, suggests an even wider field of competition,

[2] U.S. Committee on Oversight and Reform, Majority Staff Report, *Drug Pricing Investigation* 26 (Dec. 2021) https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf.

showing that Lantus's "Competitor Products" also include premixed analog insulins, such as "Humalog Mix" and "Novolog Mix."[3]

Despite these obvious potential competitors, the complaint fails to include allegations differentiating insulin glargine from other insulins and fails to allege a relevant market as a result. *See*, *e.g.*, *URL Pharma, Inc. v. Reckitt Benckiser, Inc.*, 2015 WL 5042911, at *5 (E.D. Pa. Aug. 25, 2015) (alleging distinctions between guaifenesin and other drugs). Indeed, the complaint makes only the bare assertion that "injectable insulin glargine products do not exhibit significant, positive cross-elasticity of demand with respect to price with any other insulin product." Compl. ¶ 214. Under Rule 8, however, such "bare assertions" are "not … assumed true." *Iqbal*, 556 U.S. at 681. Because Mylan fails to plausibly allege a relevant market, its monopolization and attempted monopolization claims must be dismissed.

2. *The complaint fails to allege market power.*

Mylan also fails to plausibly allege market power using either direct or indirect evidence. This is yet another independent reason for dismissing the monopolization claim in its entirety.

No direct evidence of market power. Monopoly power means that a firm "can profitably raise prices without causing competing firms to expand output and drive down prices." *Doryx*, 838 F.3d at 434. A plaintiff must therefore show "both that the defendant had an 'abnormally high price-cost margin' and that the defendant 'restricted output.'" *Id.* at 434; *see URL Pharma*, 2015 WL 5042911, at *4-5 (rejecting direct-evidence approach where complaint failed to include "any factual pleadings pertaining to … **both** supracompetitive prices and restricted output"); *Geneva Pharms. Tech. Corp. Barr Labs. Inc.*, 386 F.3d 485, 500 (2d Cir. 2004) (requiring "analysis of

[3] U.S. Senate Finance Committee, *Documents Produced by Sanofi in Insulin Investigation* 79, 237 (2021), https://www.finance.senate.gov/imo/media/doc/Sanofi_Redacted.pdf.

[the defendant's] costs" indicating an "abnormally high price-cost margin" and "evidence that the defendant restricted output"). But direct evidence is "only 'rarely available.'" *Doryx*, 838 F.3d at 434. Given this rarity, specific factual allegations are critical, because "determining whether a complaint states a plausible claim is context specific," *Iqbal*, 556 U.S. at 663, and Rule 8 does not "unlock the doors of discovery for a plaintiff armed with nothing more than conclusions," *id.* at 678-79.

While Mylan purports to chart the rare route of alleging market power based on direct evidence (Compl. ¶¶ 216-17, 219, 222), its complaint does not include any assertions indicating that Mylan has data, or even that data exists, to demonstrate market power directly. First, it never alleges Sanofi restricted output, which is fatal. Second, Mylan *admits* that an allegation that Sanofi had abnormally high margins is based only on "information and belief." Compl. ¶ 216. This amounts to "nothing more than a 'formulaic recitation of the elements'" that is "not entitled to be assumed true." *Iqbal*, 556 U.S. at 681. Mylan's other purported allegations of direct evidence of market power, in paragraph 219, merely summarize Mylan's theories of liability and do not purport to plead that Sanofi restricted output or to provide facts indicating abnormal price-cost margins. Mylan's allegations of direct evidence of market power therefore fail.

No indirect evidence of market power. Monopoly power may also be inferred from indirect evidence, but "a plaintiff typically must plead and prove that a firm has a dominant share in a relevant market, and that significant 'entry barriers' protect that market." *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 307 (3d Cir. 2007). Determining whether the defendant has a dominant market share "requires a definition of the relevant market." *Id.* And a dominant share means "significantly larger than 55%." *Doryx*, 838 F.3d at 437. Barriers to entry are factors "that prevent new competition from entering a market in response to a monopolist's supracompetitive

prices," such as "regulatory requirements, high capital costs, or technological obstacles." *Broadcom*, 501 F.3d at 307.

As discussed above, the complaint fails to define the relevant market. But even if it did, Mylan does not allege any facts describing Sanofi's share of that market (whether that be insulin glargine, basal insulin, or insulin more broadly). While the complaint contains statistics about Lantus and Toujeo sales relative to *each other*, Compl. ¶¶ 18, 209, the complaint says nothing about their share of a relevant market.

The complaint also fails to plausibly allege high barriers to entry. Its single-sentence allegation that Sanofi "enjoyed high barriers to entry" is conclusory—it does not even identify a barrier, much less plead facts in support of that conclusion. *See* Compl. ¶ 218. Mylan must plead that new market entrants "will be unable" to enter the market for specific reasons. *SEI Glob. Servs., Inc. v. SS&C Advent*, 496 F. Supp. 3d 883, 895 (E.D. Pa. 2020). But the complaint, and the Drug Pricing Report it incorporates by reference, show that Novo Nordisk, Eli Lilly, and Mylan itself have developed competing insulin glargine products and other basal insulin products and have entered the market. The complaint's conclusory allegation that new entrants will face barriers is again nothing more than a "formulaic recitation" of one of the elements. *Iqbal*, 556 U.S. at 681.

Mylan also asserts an attempted monopolization claim (*see infra* p. 25), which requires pleading that the defendant has "a dangerous probability of achieving monopoly power." *Pastore v. Bell Tel. Co. of Pa.*, 24 F.3d 508, 512 (3d Cir. 1994). Evidence of such danger dovetails with evidence of present monopoly power. The "[m]ost significant" factor "is the defendants' share of the relevant market." *Id.* at 513. Other factors include "the strength of the competition, probable development of the industry, the barriers to entry, the nature of the anti-competitive conduct, and the elasticity of consumer demand." *Id.*

Once again, even if the complaint had plausibly defined a relevant market, the complaint fails to allege Sanofi's share of it. The complaint's allegations of barriers to entry and demand elasticity are conclusory, as explained above, and the complaint says nothing about the strength of other rivals or the probable development of the industry. *See Phila. Taxi Ass'n v. Uber Techs., Inc.*, 886 F.3d 332, 342 (3d Cir. 2018) ("[E]asy entry—particularly historical evidence of entry—is even more significant in the attempt case than in monopolization cases generally.").

C. Mylan's Claim That Sanofi's Conduct Delayed FDA Approval For Semglee Is Time-Barred And Fails For Lack Of Causation

Mylan's other theory—that Sanofi improperly listed invalid patents in FDA's Orange Book and asserted those patents in litigation in order to "delay[] regulatory approval" of Semglee (Compl. ¶ 3)—fares no better. The heart of this claim arises from the Hatch-Waxman Act, which provides a pathway for "streamlining the drug approval process," as well as "specialized procedures for brand-name and generic drug manufacturers to resolve intellectual property disputes" (including the 30-month stay of FDA's approval of Semglee at issue in this case). *See In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 143-44 (3d Cir. 2017).

According to Mylan, Sanofi's Orange Book listings in 2013 somehow caused Mylan to delay seeking FDA approval of Semglee until 2017. Compl. ¶¶ 127-28. Once Mylan applied for FDA approval, Sanofi allegedly filed a sham lawsuit that triggered the statutory 30-month stay of approval of Mylan's application from October 2017 to March 2020. *See id.* ¶¶ 3, 4, 152, 157. According to Mylan, it suffered an antitrust injury because it was not able to launch Semglee "until late 2020, many years after it should have." *Id.* ¶¶ 191-93, 228. This theory fails, both because Mylan does not plausibly plead causation and because the claim is time-barred.

1. An antitrust plaintiff must establish "antitrust injury … caused by the antitrust violation—not a mere causal link, but a direct effect." *West Penn*, 147 F.3d at 268. Binding Third

Circuit precedent holds that to establish a claim for anticompetitive Hatch-Waxman litigation, a plaintiff must plead and prove that the litigation caused an injury to competition by preventing entry of a competing drug that "could have launched … in the absence of the 30-month stay." *Wellbutrin*, 868 F.3d at 151-52. Mylan fails to plausibly allege that Sanofi caused FDA to delay approval of Semglee, either by listing patents in the Orange Book in 2013 or by triggering the 30-month stay in 2017. Indeed, Mylan's own allegations, along with judicially noticeable facts from public records, flatly contradict the contention that the Orange Book listings or 30-month stay caused FDA to delay regulatory approval for Semglee or otherwise delayed Semglee's launch.

First, Mylan absurdly alleges that *Sanofi* is to blame because Mylan delayed filing its own drug application for Semglee from 2013 to 2017. Compl. ¶¶ 127-28. As the complaint explains, Mylan delayed its application because the Biologics Price Competition & Innovation Act ("BPCIA") "complicate[d] Mylan's path" to approval. *Id.* The BPCIA was enacted in 2010 and provided that regulation of certain biosimilar products approved as drugs under the Food, Drug & Cosmetic Act would transition to regulation under the Public Health Services Act ten years later, on March 23, 2020. *Id.* ¶ 56. Mylan contends that its failure to file until 2017 "would have been avoided" if not for two patents Sanofi listed in the Orange Book "by November 2013." Compl. ¶¶ 127-29. But Mylan's own allegations show that Mylan failed to file any sooner because it was engaged in a protracted dialogue with FDA about the type of application to file in light of the upcoming transition to the BPCIA. *Id.* Mylan admits that, "[a]s late as June 2016, Mylan was still inquiring of FDA whether a traditional ANDA approach, 505(b)(2), or different pathway would be appropriate for Mylan's application," Compl. ¶ 128, and that Mylan submitted its 505(b)(2) application for Semglee on April 27, 2017, "after finally receiving guidance from the FDA on the best regulatory path forward," Compl. ¶ 129. These allegations lay bare the fact that Sanofi's

patents had no logical bearing on *Mylan's* discussions with FDA or its decision about the type of drug application to file.[4] Rather, Mylan clearly had an incentive to delay filing in the hopes of convincing FDA to allow Mylan to follow the cheaper and faster ANDA route. It was this negotiation with FDA—not Sanofi's patents—that delayed Mylan's filing of its Semglee 505(b)(2) application until 2017.

Second, Mylan alleges that, once it got around to filing its drug application in 2017, the 30-month stay still acted as an impediment to Semglee's approval. Compl. ¶ 133. This is implausible for three distinct reasons.

a. To begin, Mylan does not allege, as it cannot, that FDA granted tentative approval for Semglee during the stay. Mylan acknowledges that tentative approval is the mechanism FDA uses to indicate that approval is warranted absent a stay: "The FDA may grant a 505(b)(2) application tentative approval when it determines that the application would otherwise be ready for final approval were it not for the regulatory 30-month stay. Tentative approval is granted only when the applicant satisfies all scientific and procedural preconditions to final approval." Compl. ¶ 78.[5] By its own admission, Mylan's application was not "ready for final approval" at any point during the 30-month stay. *See id.*

b. Nor can Mylan blame Sanofi for the alleged "regulatory dead zone" caused by the transition of insulin products to regulation under the BPCIA. Compl. ¶¶ 128 (heading H), 131-33. Rather, Mylan found itself in this position due to a statutory scheme and its *own delay* in filing its

[4] Mylan would have been subject to the same patent certification requirements under the Hatch-Waxman Act for any patents listed in the Orange Book and the same 30-month stay whether Mylan filed an ANDA or a 505(b)(2) application. See 21 U.S.C. §§ 355(b)(2)(A), 355(j)(2)(A)(vii).

[5] By contrast, FDA granted tentative approval to two other insulin glargine products during this time. *See* Tentative Approval Letter for Eli Lilly's Basaglar, NDA 205692 (Aug. 18, 2014), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/205692Orig1s000TAltr.pdf; Tentative Approval Letter for Merck's Lusduna, NDA 208722 (July 19, 2017), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/208722Orig1s000TAltr.pdf.

New Drug Application ("NDA")—a delay that had nothing to do with Sanofi's patents, which were in the Orange Book "by November 2013." Compl. ¶ 127. A 30-month stay does not start until after an NDA containing a paragraph IV certification is filed. Compl. ¶ 76. If Mylan had not waited so long to file its NDA, the 30-month stay would not have butted up against the BPCIA transition date in March 2020.

c. Worse yet for Mylan, publicly available FDA documents (of which the Court can take judicial notice) make clear what the complaint tries to obscure: any delay in FDA approval of Semglee was caused *not* by the 30-month stay, but by Mylan's numerous failures to comply with the overarching regulatory scheme for approving new drugs.[6] The Court may take judicial notice of these matters of public record, which are carefully omitted from the complaint despite Mylan's obvious awareness of and implicit reliance on such documents, as well as its explicit reliance on comparable FDA documents for Lantus and Toujeo. *See, e.g.*, *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993); *Starks v. Coloplast Corp.*, 2014 WL 617130, at *1 & n.3, *2 (E.D. Pa. Feb. 18, 2014) ("FDA reports published on the FDA website are public records that the court may judicially notice."); *see also* Compl. ¶¶ 136 (quoting from FDA's "approval letter" for Semglee), 95 n.22 (citing FDA's supplemental approval for Lantus), 195 n.31 (citing FDA's summary review for Toujeo). Specifically, the FDA approval documents show that Mylan delayed its own filing for over three years until April 2017 for two different reasons: (1) it was attempting to persuade FDA to award a therapeutic equivalence designation for Semglee, which would have allowed pharmacists in many states to automatically substitute

[6] *See* FDA, *Drug Approval Package*: SEMGLEE, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/210605Orig1s000TOC.cfm (last accessed September 14, 2023).

Semglee for Lantus (Compl. ¶ 81); and (2) Mylan was still conducting the studies necessary to support its application.[7]

And, after Mylan filed its NDA in April of 2017, FDA issued a "Refusal to File" decision on June 26, 2017, *because Mylan's initial application was "not sufficiently complete to permit a substantive review."*[8] As the letter explained, Mylan's application was deficient because it sought approval for an "insulin glargine product manufactured using Process VI at a facility in Malaysia (i.e., Process VI product), while the insulin glargine product studied in the Phase 3 clinical trials was manufactured using Process V at a different facility in India (i.e., Process V product)."[9] FDA deemed this a "major" "manufacturing change" that required Mylan to submit "additional clinical safety and efficacy bridging data."[10] Notwithstanding this defect—which had *nothing* to do with anything Sanofi did—Mylan requested that its application be "Filed over Protest" on August 31, 2017. Compl. ¶ 134. Over the next two years, FDA issued not one, but *two* "Complete Response Letters" stating that it "[could not] approve this application in its present form" due to "major deficiencies,"[11] including, among others, the absence of the necessary "bridging data," as well as persistent "objectionable conditions" at the Semglee manufacturing facility in Malaysia.[12] Indeed, these judicially noticeable FDA records show that FDA was still reviewing Mylan's December 16, 2019 Second Resubmission—which it filed solely to address a *second* failed inspection of the Semglee manufacturing facility—when the 30-month stay expired on March 18, 2020.

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[7] Memorandum of Meeting Minutes at 2-3, 8, 11 (Mar. 7, 2014) (**Exhibit B**), in FDA, Administrative and Correspondence Documents, IND 105279/NDA 210605, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/210605Orig1s000AdminCorres.pdf (hereinafter "Administrative Correspondence").

[8] Refusal to File Letter at 1 (Jun. 26, 2017) (**Exhibit C**), in Administrative Correspondence.

[9] *Id.*

[10] *Id.*

[11] Complete Response Letter at 1 (May 17, 2018) (**Exhibit D**), and Complete Response Letter at 1 (Aug. 28, 2019) (**Exhibit E**), in FDA, Other Action Letters, NDA 210605, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/210605Orig1s000OtherActionLtrs.pdf.

[12] Exhibit D at 1-2; Exhibit E at 1.

In sum, the 30-month stay had no bearing on the timing of FDA approval for Semglee. Mylan's conclusory and speculative allegations to the contrary, which conflict with other allegations in the complaint and FDA's public records, fail to move the causation needle from impossible to "conceivable," let alone to actionable. *Twombly*, 550 U.S. at 555, 570. Thus, Mylan's claims must be dismissed to the extent they are based on any allegations that Sanofi caused FDA to delay approval of Semglee. *See West Penn*, 147 F.3d at 268 (affirming dismissal of antitrust complaint because "the interposition of the regulatory scheme and actions of the parties … interferes with the chain of causation"); *Wellbutrin*, 868 F.3d at 152-53 (rejecting argument that patent lawsuit "delayed Abrika's entry into the market" because there is "no evidence that Abrika could have launched even in the absence of the 30-month stay"); *id.* at 166 (reiterating that "no antitrust standing exists when a plaintiff's grievance is caused by a regulatory scheme rather than by the defendant's actions.").

2. Even if Mylan had adequately pleaded causation, its Orange Book-related claim would be barred by the statute of limitations. Under both federal and state law, an antitrust claim must be brought within four years of accrual, and a claim "accrues … when a defendant commits an act that injures a plaintiff's business." *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 401 U.S. 321, 338 (1971); *see* 15 U.S.C. § 15b; N.J. STAT. ANN. §§ 56:9-14. "[T]he statute of limitations runs from the commission of the act." *Zenith Radio*, 401 U.S. at 338. Here, Mylan filed its complaint on May 17, 2023, which means the alleged "act" that injured Mylan must have been committed *after* May 17, 2019, for the complaint to fall within the statute of limitations.

Mylan alleges two acts by Sanofi that supposedly caused FDA to delay approval of Semglee, both of which occurred well before May 17, 2019: (1) the allegedly improper listing of patents in the Orange Book "by November 2013" (Compl. ¶¶ 127-28); and (2) the allegedly sham

patent infringement litigation filed on October 24, 2017. Compl. ¶¶ 145-46, 152. As to the latter, it makes no difference that the lawsuit progressed after October 2017, or that the stay was in effect for 30 months. "[T]he limitation period for monopolization by a wrongfully filed lawsuit runs from either the date the suit is filed or the date that the suit's defendant receives the process." Areeda & Hovenkamp ¶ 320; *P & M Servs., Inc. v. Gubb*, 2008 WL 4185903, at *5 (E.D. Mich. Sept. 8, 2008) ("[T]he operative overt act for purposes of the antitrust limitations statute is the filing of the sham lawsuit"), *aff'd*, 372 F. App'x 613 (6th Cir. 2010). As the Fifth and Ninth Circuits have explained, any "injury … resulting from continued prosecution" of the lawsuit "relates back to the initial decision to file." *Al George, Inc. v. Envirotech Corp.*, 939 F.2d 1271, 1274 (5th Cir. 1991) (quoting *Pace Indus. v. Three Phoenix Co.*, 813 F.2d 234, 238-39 (9th Cir. 1987)). Accordingly, whenever the supposed delay occurred, the claim for sham litigation accrued in October 2017 and is time-barred.[13]

D. Mylan's Sham Litigation Allegations Fail *Twombly*

Separately, the allegations of sham litigation must be dismissed because the complaint fails to allege facts that would overcome the First Amendment protection afforded to Sanofi's patent

[13] An unpublished decision of the Third Circuit also supports this argument. In *Perrigo Co. v. AbbVie Inc.*, the plaintiff asserted a monopolization claim based on sham litigation triggering a 30-month FDA stay. 2022 WL 2870152, at *4 (3d Cir. July 21, 2022). The court held that claim accrued "as soon as Defendants filed the Litigation." *Id.* at *4; *see id.* at n.10 ("The filing of a baseless lawsuit triggers the statute of limitations for antitrust claims based on that lawsuit."). As such, Mylan's alleged claim necessarily accrued on October 24, 2017, and is time-barred. Some language in the opinion, however, goes further and suggests that the triggering of a 30-month stay "necessarily delay[s] FDA approval." *Id.* at *4. But *Perrigo*'s reasoning in this regard conflicts with the published holding of the Third Circuit in *Wellbutrin*, 868 F.3d at 152-53. In *Wellbutrin*, the Third Circuit ruled that to prevail on a sham litigation claim a plaintiff must prove that the litigation caused antitrust injury by delaying a competing drug that "could have launched … in the absence of the 30-month stay." Further, the Court held that the 30-month stay in that case did not delay the competing drug because "FDA could not have approved" it absent the 30-month stay due to other regulatory bars. *Id.* at 151-53. In light of these authorities it is clear that (1) the limitations period begins to run when a sham lawsuit triggers the 30-month stay, *Perrigo*, 2022 WL 2870152, at *4 n.10; (2) any injury from delayed drug approval "relates back to the initial decision to file" the lawsuit, *Al George*, 939 F.2d at 1274; and (3) in all cases, a plaintiff must prove causation by showing that a competing drug "could have launched … in the absence of the 30-month stay," *Wellbutrin*, 868 F.3d at 151-52.

litigation under the Supreme Court's *Noerr-Pennington* doctrine. To overcome that immunity, a plaintiff must establish that the lawsuit was both "objectively baseless"—meaning the litigant had no "probable cause to initiate a suit"—and subjectively motivated by anticompetitive intent. *Wellbutrin*, 868 F.3d at 147. A plaintiff faces an especially "high[]" burden when alleging that patent litigation involving FDA approved drugs was "objectively baseless." *Id.* at 144, 149-51. Under the Hatch-Waxman Act, a drug applicant's "paragraph IV certification" that any relevant patents are invalid or not infringed "automatically counts as patent infringement." *Id.* at 144 (citing 21 U.S.C. § 355(j)(2)(A)(vii)); *see also* Compl. ¶¶ 70, 74, 76 (explaining paragraph IV certifications). Thus, a patent infringement suit under the Hatch-Waxman Act "could only be objectively baseless if no reasonable person could disagree with the assertions of noninfringement or invalidity in the certification." *Wellbutrin*, 868 F.3d at 149.

Mylan's allegations do not remotely approach (never mind meet) this standard. Mylan alleges that it sent a letter "notifying Sanofi it had filed … paragraph IV certifications and explaining its positions." Compl. ¶ 144. But the complaint fails to disclose the contents of Mylan's certification, and Mylan does not even attempt to allege that "no reasonable person could disagree" with its paragraph IV "assertions of noninfringement or invalidity." *Wellbutrin*, 868 F.3d at 149. Mylan's boilerplate allegations are insufficient to state a claim as a matter of law. *E.g.*, *Takeda Pharm. Co. v. Zydus Pharms. (USA) Inc.*, 2021 WL 3144897, at *12 (D.N.J. July 26, 2021) ("A boilerplate noninfringement assertion in an ANDA is insufficient to demonstrate objective baselessness"), *aff'd*, 2022 WL 17546949 (3d Cir. Dec. 9, 2022).

Mylan also asserts that the patents were *later* determined to be invalid by the Patent Trial and Appeal Board. Compl. ¶¶ 152-87. But an allegation that patents were *later* invalidated does *not* mean that asserting them in litigation was objectively bas eless from the start. *See Prof'l Real*

Est. Inv'rs, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 60 n.5 (1993) ("[A] court must resist the understandable temptation to engage in *post hoc* reasoning by concluding that an ultimately unsuccessful action must have been unreasonable." (cleaned up)). The U.S. PTO examined the patent claims and issued every one of Sanofi's applications, after "thorough examination." *See* 37 C.F.R. § 1.104(a)(1); *Hyatt v. U.S. PTO*, 110 F. Supp. 3d 644, 646 (E.D. Va. 2015) (describing the "iterative process" of the patent examiner's "thorough examination"). Once issued, patents are "presumed valid" by statute (35 U.S.C. § 282(a)), and a patentee has an objective basis to presume the patent is valid *unless and until* it is later adjudicated invalid by a court or the PTO. *Commil USA, LLC v. Cisco Sys., Inc.*, 575 U.S. 632, 643 (2015) ("That presumption takes away any need for a plaintiff to prove his patent is valid to bring a claim."). Further, Mylan's allegations must be evaluated in light of the judicial record concerning those patents, which includes a strong dissent from one of the Federal Circuit judges serving on the panel reviewing the PTAB's invalidation of two of the patents. *See Sanofi-Aventis Deutschland GMBH v. Mylan Pharms. Inc.*, 791 F. App'x 916, 929-32 (Fed. Cir. 2019) (Newman, J., dissenting). It is not plausible to allege that it was objectively baseless for Sanofi to assert its patents in litigation when they were issued by the PTO, presumed valid by statute, and when at least one Federal Circuit judge deemed them valid. What's left is only the allegation that Sanofi had no "reasonable expectation of winning," Compl. ¶¶ 140, 146, a conclusory allegation that cannot survive *Twombly*. Mylan has failed to state a sham litigation claim.

* * *

Mylan's two theories of monopolization—using bundled discounts and delaying FDA approval of Semglee—fail for all the reasons stated above. This is true whether these theories are considered independently or as components of what Mylan calls a "multifaceted monopolization

scheme." Compl. ¶¶ 3, 236. As the Supreme Court has explained, a plaintiff cannot allege one claim "that cannot succeed with a [second] claim that cannot succeed, and alchemize them into a new form of antitrust liability." *linkLine*, 555 U.S. at 457. "Two wrong claims do not make one that is right." *Id.* Mylan's monopolization claim must be dismissed entirely.

II. MYLAN'S BACKUP CLAIMS MUST BE DISMISSED AS WELL

A. Mylan Fails To State A Claim For Attempted Monopolization, Exclusive Dealing Under Clayton Act Section 3, Or Violation Of New Jersey Antitrust Law

For all the same reasons discussed above, Mylan fails to state a claim in Counts II-IV. For an attempted monopolization claim under section 2 of the Sherman Act, a plaintiff must show "that the defendant (1) had specific intent to monopolize the relevant market, (2) engaged in anti-competitive or exclusionary conduct, and (3) possessed sufficient market power to come dangerously close to success." *Barr Labs., Inc. v. Abbott Labs.*, 978 F.2d 98, 112 (3d Cir. 1992). The plaintiff must also plead antitrust injury and causation. *West Penn*, 147 F.3d at 265. As explained above (*supra* pp. 16-24), the complaint fails to plead causation of any delay in FDA approval of Semglee, and fails to plead the sham litigation theory. It also fails to plead exclusive dealing through bundled discounts and substantial market foreclosure. *Supra* pp. 3-9. Finally, it fails to plead a dangerous probability of market power in a relevant market, which requires dismissal of the entire claim. *Supra* pp. 10-15. Of course, lacking any of these well-pleaded allegations, the complaint also fails to plausibly allege a specific intent to monopolize; Mylan's conclusory allegations of specific intent are insufficient.

For the exclusive dealing claim under section 3 of the Clayton Act, "the applicable law is the same" as under section 2 of the Sherman Act. *Eisai*, 821 F.3d at 402 & n.11. For the reasons stated above (*supra* pp. 3-9), the complaint fails to plead any form of exclusive dealing conduct, and fails to plead substantial market foreclosure.

And for the New Jersey state claim, New Jersey courts "follow federal antitrust law in interpreting [New Jersey's] antitrust statute." *Sickles v. Cabot Corp.*, 877 A.2d 267, 270-71 (N.J. Super. Ct. App. Div. 2005). Accordingly, the state claim must be dismissed for the same reasons given above.

B. Mylan Fails To State A Claim For Tortious Inducement Of Refusal To Deal

The complaint also fails to state a claim "for common law liability for tortious inducement of refusal to deal." Compl. ¶ 257. The complaint does not even allege which state law Sanofi supposedly violated, much less plead the elements of a claim under that unspecified source of state law. Assuming for the sake of argument only that Pennsylvania law applies, the complaint fails to allege any specific prospective contractual relationships—the first element of a claim for interference with prospective contractual relations. *See, e.g.*, *Salsgiver Commc'ns, Inc. v. Consol. Commc'ns Holdings, Inc.*, 150 A.3d 957, 964 (Pa. Super. Ct. 2016). A prospective contractual relationship is "something less than a contractual right, something more than a mere hope." *Thompson Coal Co. v. Pike Coal Co.*, 412 A.2d 466, 471 (Pa. 1979). It requires a "reasonable likelihood or probability" that a contract would have arisen absent the alleged interference. *Id.* (quoting *Glenn v. Point Park Coll.*, 272 A.2d 895, 898-99 (Pa. 1971)).

Here, the complaint merely states that "Mylan had a reasonable expectation of economic benefit from prospective contractual and economic relationships with thousands of purchasers, pharmacies, and diabetic patients across the country, all of whom would purchase Mylan's Semglee." Compl. ¶ 258. Nowhere, however, does Mylan identify these "thousands" of purchasers by name or with any degree of particularity. *See Alvord-Polk, Inc. v. F. Schumacher & Co.*, 37 F.3d 996, 1015 (3d Cir. 1994) (affirming summary judgment on tortious interference claim where plaintiffs "failed to identify with sufficient precision contracts and prospective contracts which were interfered with by the defendants"). Nor does Mylan plead any facts

supporting its conclusion that "all" of the unidentified purchasers would have purchased Semglee had they not been "induced into not dealing with Mylan" by Sanofi. *Id.* ¶ 260. Such vague and conclusory allegations fail *Twombly*, 550 U.S. at 555. Moreover, they reflect nothing more than Mylan's "mere hope" of prospective contractual relationships, as opposed to the "reasonable likelihood or probability" required to state a claim. *Thompson*, 412 A.2d at 471; *see also McLaughlin v. Int'l Bhd. of Teamsters*, *Local 249*, 641 F. Supp. 3d 177, 223 (W.D. Pa. Sept. 6, 2022) (dismissing tortious inducement claim based on plaintiff's "fail[ure] to set forth sufficient facts to establish a prospective employment relationship").

III. THE COMPLAINT IS AN IMPERMISSIBLE SHOTGUN PLEADING

The complaint is an impermissible shotgun pleading that fails to comply with Rule 8(a)(2). A shotgun pleading, among other things, "asserts multiple claims against multiple defendants without specifying which of the defendants are responsible for which acts or omissions." *Bartol v. Barrowclough*, 251 F. Supp. 3d 855, 859 (E.D. Pa. 2017) (cleaned up); *see also Hynson v. City of Chester, Legal Dep't*, 864 F.2d 1026, 1031 n.13 (3d Cir. 1988) (criticizing "shotgun pleading"). This fails "to give the defendants adequate notice of the claims against them and the grounds upon which each claim rests." *Bartol*, 251 F. Supp. 3d at 859; *see also Caristo v. Blairsville-Saltsburg Sch. Dist.*, 370 F. Supp. 3d 554, 569 n.21 (W.D. Pa. 2019) (Hornak, J.) ("Plaintiff must plead facts demonstrating the specific personal involvement of each Individual Defendant.") (collecting cases).

The opening paragraph of the complaint contains an unabashed mashup of three distinct Plaintiffs and four distinct Defendants: "Plaintiffs Mylan Pharmaceuticals Inc., Mylan Specialty L.P., and Mylan Inc. (collectively 'Mylan') bring this Complaint against Sanofi S.A., Sanofi-

Aventis U.S. LLC, Aventis Pharma S.A.,[14] and Sanofi-Aventis Puerto Rico Inc. (collectively 'Sanofi')." Compl. Intro. Thereafter, over 265 paragraphs and 5 counts, the complaint refers generally to "Mylan" and "Sanofi" without ever distinguishing which entity or entities allegedly did what and to which other entity or entities. By "[l]umping" the parties together, the complaint "fails to put Defendants on notice of their own alleged wrongdoing." *Campbell v. City of New Brunswick*, 2018 WL 2234899, at *3 (D.N.J. May 16, 2018); *see also Grande v. Starbucks Corp.*, 2019 WL 1455445, at *3 (E.D. Pa. Apr. 2, 2019) ("The defendants cannot defend the claims against them if they do not know which acts they allegedly committed and where those acts allegedly occurred.").

The complaint's melding of the various defendants also obscures the factual allegations necessary for the Court to determine whether Mylan has alleged plausible claims against each defendant as necessary under Rule 8. *See Ezekwo v. Jacobs*, 2023 WL 3848332, at *2 (D.N.J. June 6, 2023) (appeal pending) ("Such group pleading is also inappropriate and grounds for dismissal … because 'when defendants are grouped together, a court cannot determine whether a complaint has set forth plausible allegations as to each particular defendant.'"); *Mensah v. Manning*, 2020 WL 91089, at *6 (D.N.J. Jan. 8, 2020) ("[T]he Amended Complaint provides no other factual allegations of any acts specifically undertaken by any Defendant that would connect them to Plaintiff's alleged injuries, much less that would give rise to a plausible claim for relief.").

Here, Mylan alleges that the four Defendants, collectively defined, committed antitrust violations by improperly listing patents and litigating infringement claims, and by bundling rebates

[14] The complaint incorrectly identifies this defendant as "Aventis Pharma S.A." In December 2020, the form and name of the company changed under French law from a société anonyme ("S.A.") to a société à responsabilité limitée ("S.A.R.L."). Similarly, the complaint incorrectly uses the name "Sanofi S.A." While that entity is organized under French law as a société anonyme, the corporate designation "S.A." is not part of the entity's name. Nonetheless, for the avoidance of confusion, we refer to the two French defendants by the names used for them in the complaint: Sanofi S.A. and Aventis Pharma S.A.

for Toujeo and Lantus, but the complaint provides *no* indication whether or how each individual defendant participated in the alleged patent abuse or alleged monopolization. Indeed, the only fact individually alleged about Sanofi S.A. or Aventis Pharma S.A. is that each company conducts business *in France*. *See* Compl. ¶ 27 (alleging that Sanofi S.A.'s "principal place of business" is in "France"), ¶ 29 (same as to Aventis Pharma S.A.). The complaint is devoid of any factual allegations regarding how these entities, headquartered in France, participated in the alleged antitrust violations in the United States. The complaint does not even attempt to provide a plausible basis for Plaintiffs' claims against them.

Because Mylan's shotgun complaint fails to give the defendants notice as to conduct alleged against each, and because it falls short of the requirements of Rule 8 as to each defendant, the complaint should be dismissed in full. *See, e.g.*, *Grande*, 2019 WL 1455445, at *2-3; *Campbell*, 2018 WL 2234899, at *3; *Bartol*, 251 F. Supp. 3d at 859-61.

IV. MYLAN FAILS TO ALLEGE PERSONAL JURISDICTION OVER SANOFI S.A.

Relatedly, because it is a group pleading lacking any specific allegations as to any defendant, the complaint fails to plausibly allege that this Court has personal jurisdiction over French defendant Sanofi S.A. That defendant therefore moves to dismiss for lack of personal jurisdiction under Federal Rule of Civil Procedure 12(b)(2).

Consistent with due process, a court lacks personal jurisdiction over a defendant unless that defendant has sufficient "minimum contacts" with the forum. *D'Jamoos ex rel. Estate of Weingeroff v. Pilatus Aircraft Ltd.*, 566 F.3d 94, 102 (3d Cir. 2009). The relevant forum for purposes of this litigation is "the United States as a whole." *In re Auto. Refinishing Paint Antitrust Litig.*, 358 F.3d 288, 298 (3d Cir. 2004) (explaining the statutory basis for holding that "personal jurisdiction in federal antitrust litigation is assessed on the basis of a defendant's aggregate contacts with the United States as a whole.").

To evaluate minimum contacts, "[e]ach defendant's contacts with the forum … must be assessed individually." *Nicholas v. Saul Stone & Co. LLC*, 224 F.3d 179, 184 (3d Cir. 2000); *see Bristol-Myers Squibb Co. v. Super. Ct. of Cal., S.F. Cty.*, 582 U.S. 255, 268 (2017) (minimum contacts "must be met as to each defendant"). Further, jurisdiction over a local subsidiary does not establish jurisdiction over a foreign parent "because of the presumption of corporate separateness." *In re Enter. Rent-A-Car Wage & Hour Emp't Practices Litig.*, 735 F. Supp. 2d 277, 317 (W.D. Pa. 2010); *Daimler AG v. Bauman*, 571 U.S. 117, 134-35 (2014) (describing rule that "a subsidiary's jurisdictional contacts can be imputed to its parent only when the former is so dominated by the latter as to be its alter ego.").

"Once a defendant challenges a court's exercise of personal jurisdiction over it, the plaintiff bears the burden" to "'establish a prima facie case of personal jurisdiction.'" *D'Jamoos*, 566 F.3d at 102. Establishing a prima facie case requires that the plaintiff allege "the nature and extent" of each defendant's contacts with the forum "with reasonable particularity." *Gehling v. St. George's Sch. of Med., Ltd.*, 773 F.2d 539, 542 (3d Cir. 1985).

A plaintiff cannot satisfy this burden by lumping multiple defendants together into an undifferentiated mass, a tactic making it impossible to discern each defendant's alleged contacts with the forum. Courts have repeatedly dismissed complaints on that basis. In *Heartrepreneur, LLC v. Jones*, for example, the plaintiff alleged that six out-of-state defendants targeted in-state consumers, but the complaint "refer[ed] to all Defendants collectively and [did] not separately allege how each Defendant purposefully directed activities towards Pennsylvania." 2020 WL 2839102, at *3 (E.D. Pa. June 1, 2020). The court rejected that approach as insufficient under Supreme Court precedent: "Plaintiffs may not simply lump Defendants together to establish jurisdiction." *Id.* (citing *Calder v. Jones*, 465 U.S. 783, 790 (1984)). Similarly, in *Truinject Corp.*

v. Nestlé Skin Health. S.A., the plaintiff "attempt[ed] to create the impression that Nestlé Skin Health, S.A.'s role was significant by collectively defining all of the Corporate Defendants as 'Nestlé Skin Health' in the Complaint." 2020 WL 1270916, at *3 (D. Del. Mar. 17, 2020). The court rejected that approach, explaining that the collective definition made it "extremely difficult … to discern from the Amended Complaint which Defendant performed the alleged acts." *Id.* The court therefore granted the motion to dismiss: "Truinject's group pleading has resulted in a complaint that fails to meet its burden to allege sufficient facts to establish that this Court may properly exercise personal jurisdiction over Nestlé Skin Health, S.A." *Id.*; *see also Epstein v. Goodman Mfg. Co., LP*, 2015 WL 502033, at *4 (D.N.J. Feb. 4, 2015) ("[N]owhere in its brief does Elica specifically argue that SKF–Italy is subject to this Court's jurisdiction standing alone."); *id.* at *5 ("[T]o accept Elica's argument would be tantamount to disregarding the corporate form of over 80 entities.").

Here, the complaint's allegations regarding personal jurisdiction fall far short of being reasonably particular as to each defendant. The complaint's only individualized allegations as to Sanofi S.A. is that it is incorporated and headquartered *in France*, not the United States. Compl. ¶ 27. Thus, the complaint clearly fails to allege that Sanofi S.A. is "at home" in the United States for purposes of general personal jurisdiction. *See Daimler*, 571 U.S. at 138-39 (rejecting general personal jurisdiction because "neither Daimler nor MBUSA is incorporated in California, nor does either entity have its principal place of business there.").

Nor does the complaint make a prima facie case of specific personal jurisdiction over Sanofi S.A. based on contacts "[giving] rise to the liabilities sued on." *Id.* at 126. The remainder of the complaint's personal jurisdiction allegations do not distinguish among the defendants, instead alleging that the court has personal jurisdiction over "Sanofi," defined as all four

defendants. Compl. ¶¶ 31, 33-36. In support, the complaint alleges that "Sanofi"—again undifferentiated—manufactured, sold, and shipped Lantus and Toujeo in interstate commerce. *Id.* ¶ 34. The complaint also alleges, with no individual specificity, that "Sanofi" transacts business in the United States and that its actions were "directed at" the United States. *Id.* ¶¶ 35-36. The rest of the complaint's allegations use the same collective definition.

None of these paragraphs contain any factual allegations regarding Sanofi S.A.'s contacts with the United States. The use of the undifferentiated term "Sanofi" is blatantly inadequate to plead minimum contacts as to each defendant. Mylan may not "simply lump Defendants together to establish jurisdiction," *Heartrepreneur*, 2020 WL 2839102, at *3, because each defendant's contacts "must be assessed individually," *Nicholas*, 224 F.3d at 184. The complaint offers no plausible basis to conclude that Sanofi S.A.—a holding company that neither manufactures, markets, nor sells products—conducts any business whatsoever in the United States. Nothing else in the complaint identifies any activities that this defendant undertook anywhere, let alone in the United States. The complaint must therefore be dismissed as to Sanofi S.A. for lack of personal jurisdiction under Federal Rule of Civil Procedure 12(b)(2).

CONCLUSION

For the foregoing reasons, the Court should dismiss the complaint.

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Respectfully submitted,

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